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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,732	02/06/2001	Yingyos Avihingsanon	01948-059001	8709

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BOSTON, MA 02110

EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 02/27/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/777,732

Applicant(s)

Avihingsanon et al.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 9, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above, claim(s) 12-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) is/are objected to.
- 8) ☒ Claims 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. .
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s), 9&10 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group I, claims 1-11 in Paper No. 15 is acknowledged.
2. Claims 12-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group II-IV, claims 12-34, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 15.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-6, 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soares et al. (Nature Medicine, 1998, Vol. 4(9), pg. 1073-1077).

Soares et al. disclose that the expression of the heme oxygenase-1 (HO-1) is functionally associated with xenograft survival and that rapid expression of HO-1 in cardiac xenografts can be essential to ensure long-term xenograft survival (See pg. 1073, the Abstract). The gene expression of HO-1 is also determined by immunocytochemistry and by reverse transcriptase (See pg. 1073, column 1, first paragraph). Expression of HO-1 was also detected in xenograft undergoing rejection (See pg. 1073, column 1, first paragraph). Soares et al. further address that expression of HO-1 by xenograft endothelial cells as in hearts from HO-1^{+/+} mice counteracts the xenograft rejection (See pg. 1076, second paragraph).

One of ordinary skill in the art at the time of the instant invention would have been motivated to evaluate acute transplant rejection in a host by determining the expression of the cytoprotective gene cluster with comparing the baseline of the gene expression of the protective gene and detecting the upregulation of the protective gene because of the study of expression of HO-1 in cardiac xenografts as disclosed by Soares et al., and the detection of the expression of HO-1 in xenograft undergoing rejection (See pg. 1073, column 1, first paragraph). It would have been prima facie obvious to carry out the method as claimed.

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5. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bach et al. (Nature Medicine, 1997, Vol. 3(2), pg. 106-204) and claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Soares et al. (Nature Medicine, 1998, Vol. 4(9), pg. 1073-1077) as applied to claims 1-6 and 8-9 above, and also further in view of Bach et al. (Nature Medicine, 1997, Vol. 3(2), pg. 106-204) .

The teachings of Soares et al. are set forth in section 4 above.

Soares et al. do not explicitly disclose the protective gene, A20 which is involved in the survival of xenografts.

Bach et al. disclose that the protective gene of the endothelial cells prevent the cells from undergoing apoptosis. A20 and bcl-X have been studied (See pg. 197, column 1). Bach et al. further disclose that Organs that were rejected expressed these genes products weakly in only very occasional endothelial cells (See pg. 202, column 1, first paragraph).

One of ordinary skill in the art at the time of the instant invention would have been motivated to evaluate acute transplant rejection in a host by detecting the gene expression of protective gene A20 because Bach et al. disclose that Organs that were rejected expressed these genes products weakly in only very occasional endothelial cells (See pg. 202, column 1, first paragraph). The indication of Bach et al would have motivated one of ordinary skill in the art to determine the gene expression of the protective gene, A20 and HO-1 for evaluating acute transplant rejection. It would have been prima facie obvious to carry out the method as claimed.

Summary

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6. No claims are allowable.
7. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

IT
February 21, 2003


GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600